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-6-

REMARKS

This is responsive to the Office Action mailed on August 28, 2006. The Office Action indicates that claims 1-5, 8-11, and 16-27 are currently pending in the application. In the Office Action, claims 1-5, 8-11, and 16-27 are rejected. Applicants have amended claims 1-5, 10, 11, 23 and 25, and canceled claim 16. New claims 41-46 have been added. No new matter has been added. The application currently includes claims 1-5, 8-11, 16-27 and 41-46.

The Office Action rejected claims 1-5, 9-11, and 16-27 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Office Action alleges that in the instant Application the claims are directed to a composite matrix comprising a first layer and a second layer, each layer having a flexibility modifying agent in specified quantities, and wherein the flexibility modifying agent comprises an elastic protein. The Office Action alleges with regard to the flexibility modifying agent, the specification teaches that the flexibility modifying agent can be bio-macromolecules, such as elastin and proteoglycans, or synthetic polymers at page 19, lines 11-15. The Office Action alleges that no further species or examples of proteoglycans or synthetic polymers are provided.

The Office Action alleges that Applicants have limited the flexibility modifying agent to agents which comprises an elastic protein, yet the instant disclosure allegedly fails to provide sufficient written description of a representative number of species of elastic proteins which is required to claim the genus of elastic protein. The Office Action alleges that the only discussion of elastic proteins is found on page 22 of the specification wherein Applicants teach "additional components can be added to the composite to alter the mechanical properties of a layer. For example, a layer can include elastin and similar proteins to impart elasticity to the layer. Suitable proteins can be called elastic proteins."

The Office Action alleges that Applicants continue to describe the structure of elastin, but

- 7 -

are silent with regards to other suitable proteins which fall into the genus of elastic proteins. The Office Action then concludes that Applicants are limited to the single species of elastin, as the only flexible modifying agent.

Applicants respectfully disagree that the claim term "elastic protein" is limited to only elastin. Applicants submit that at page 22, lines 12-13, Applicants have disclosed that an elastic protein can be an engineered protein that mimics the properties of elastin. Applicants submit that the properties of elastin are known, therefore, any engineered protein having properties similar to elastin would also fall within the scope of the claim. Further, at page 22, lines 11-12, the Application discloses that a suitable elastic protein can also be a natural protein, where one natural protein is disclosed as silk. Therefore, Applicants submit that the specification has defined an elastic protein as including more than elastin, and includes engineered proteins and natural proteins that mimic the properties of elastin. As such, Applicants respectfully request that the 35 U.S.C. §112, first paragraph, rejection of claims 1-5, 9-11, and 16-27 be withdrawn.

The Office Action also rejected claims 1-5, 8-11, and 16-27 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office Action alleges that Applicants' claim are directed to a composite matrix comprising a first layer and a second layer, each layer having a flexibility modifying agent, the first layer having at least about 5 dry weight percent flexibility modifying agent and the second layer having at least about 5 dry weight percent less flexibility modifying agent than the first layer, wherein the at least one layer comprises a reconstituted composition, and wherein the flexibility modifying agent comprises an elastic protein. The Office Action alleges in claim 1 that it is unclear whether the flexibility modifying agent, which is to comprise an elastic protein, must be the same agent in each of the first and second layers. If the flexibility modifying agent is to be the same in the first and second layers, it would be remedial to adopt the language "wherein said first/second layers comprise at least X amount of said flexibility modifying agent."

The Office Action also alleges that claim 1 is not clear as to what is meant by "reconstituted composition", and it is not clear if the reconstituted composition is to be in addition to the flexibility

- 8 -

modifying agent or if the flexibility modifying agent is to be the reconstituted composition. If the reconstituted composition is to be in addition to the flexibility modifying agent, it would be remedial to change the language to "wherein at least one of said layers further comprises a reconstituted composition."

Applicants respectfully disagree that claim 1 fails to meet the requirements of 35 U.S.C. §112, second paragraph. Applicants have amended claim 1 to clarify that the flexibility modifying agent in at least one of the layers comprises an elastic protein. As defined in the Application, at page 22, an elastic protein can be a natural protein as well as an engineered protein wherein both the natural proteins and engineered proteins mimic the properties of elastin. Therefore, Applicants submit that the flexibility modifying agent in the first and second layers may be of different compositions that are defined by a weight percent difference in the layers. As such, Applicants submit that they have particularly pointed out and distinctly claimed the present invention. With respect to the reconstituted composition, Applicants have adopted the Office Action's recommendation wherein Applicants are claiming that at least one layer further comprises a reconstituted composition.

In light of the Amendment to claim 1, and the argument provided with respect to what is defined as an elastic protein, Applicants respectfully submit that the 35 U.S.C. §112, second paragraph, rejection has been traversed. Applicants respectfully request that the 35 U.S.C. §112, second paragraph, rejection be withdrawn with respect to claim 1.

The Office Action also rejected claims 2-5 under 35 U.S.C. §112, second paragraph, and alleges that claims 2-5 require the second layer to comprise collagen in different forms and/or amounts. The Office Action alleges that because collagen is not considered to be a flexibility modifying agent, it appears that collagen is to be an additional component. The Office Action mentioned it would be clear to modify the language of each of the claims to read "wherein the second layer further comprises."

Applicants submit they have adopted the suggested claim language for claims 2-5. Therefore, Applicants respectfully request that the 35 U.S.C. § 112, second paragraph, rejection be withdrawn.

-9-

The Office Action also rejected claims 10, 23, 25, and 27 as teaching additional components and thus for clarity should read "wherein the first layer further comprises." Applicants submit that they have amended claims 10, 23, and 25 to comply with the suggested claim language to overcome the 35 U.S.C. § 112, second paragraph, rejection. However, Applicants submit that claim 27 already includes the further comprising language and therefore respectfully submits that claim 27 complies with 35 U.S.C. § 112, second paragraph. Applicants respectfully request that the rejections of claims 10, 23, 25 and 27 under 35 U.S.C. § 112, second paragraph, be withdrawn.

The Office Action also rejected claim 16 under 35 U.S.C. § 112, second paragraph as being unclear because claim 1, as amended, now requires the flexibility modifying agent to comprise an elastic protein and claim 16 still requires the addition of elastic proteins. The Office Action suggested amending to delete elastic protein but that the change would make claim 16 a substantial duplicate of claim 11.

In response to the 35 U.S.C. § 112, second paragraph, rejection, Applicants have canceled claim 16. Applicants request that the rejection be withdrawn.

The Office Action also rejected claim 26 under 35 U.S.C. § 112, second paragraph because the Office Action alleges it is not clear what is included as an attachment compound for fibroblast precursor cells for vascular and endothelial precursor cells. Applicants submit that attachment compounds are discussed at page 29, line 20-page 31, line 24. As such, Applicants respectfully submit that Applicants have provided disclosure which provides the basis for the subject matter claimed in claim 26. Applicants respectfully request that the 35 U.S.C. § 112, second paragraph, rejection of claim 26 be withdrawn.

The Office Action rejected claims 1-4, 8-11, 16, and 20-27 as being anticipated by Ryan, International Publication WO 00/35372. With respect to independent claim 1, the Office Action alleges that Ryan teaches a method of producing a multilayered blood vessel prosthesis thereby produced. The Office Action alleges that Ryan teaches a multilayered blood vessel prosthesis that includes (i) an inner layer comprising type I collagen, type IV collagen, GAG, elastin and laminin; and (ii) an outer layer comprising type I collagen, GAG, elastin and fibronectin.

With regard to the elastin content, the Office Action alleges that the Ryan application

-10-

teaches each matrix can include up to 30% by weight elastin, preferably between 5 and 20%. The Office Action further alleges that the Ryan application further teaches that each of the layers/tubes can be manufactured such that the chemical and/or physical compositions are different in each of the tubes, specifically Ryan teaches the inner layer/tube can have a higher concentration of elastin compared to the outer layer/tube. The Office Action alleges that the instant claims require the second layer to have 'at least about 5 dry weight percent less flexibility modifying agent (elastin) than the first layer', however, because the phrase 'at least about 5 dry weight percent' is not definite, any difference in the elastin concentration between the first and second layers is considered to read on the instant claims. The Office Action finally alleges that because the Ryan application teaches an elastin concentration ranging from 5 to 20% in each matrix layer, wherein the inner layer (first layer) has a higher concentration of elastin than the outer layer (second layer), the difference between the elastin concentrations is considered to be 'at least about 5%', and therefore the Office Action alleges that claim 1 is anticipated.

Applicants respectfully disagree that claim 1 is anticipated by the Ryan application. Claim 1 includes that at least one layer further comprises a reconstituted composition. Reconstituted compositions are defined as involving mixtures of synthetic and/or purified materials, possibly blended with fragmented natural materials, to form a non-natural material for incorporation into the composite. (See page 16, lines 16-19 of the application). The Office Action makes no allegation that the Ryan application discloses a reconstituted composition, and Applicants submit that the Ryan application does not disclose a reconstituted composition as defined in the application.

Since the Ryan application does not disclose each and every element of claim 1, namely a reconstituted composition, claim 1 is not anticipated by the Ryan application. Reconsideration and allowance of claim 1 are respectfully requested.

The Office Action also rejected dependent claims 2-4, 8-11, 16 and 20-27 for the reasons stated with respect to independent claim 1 as well as other passages in the Ryan Application. While Applicants do not acquiesce to these rejections of the above-mentioned dependent claims, the rejections are moot in light of the fact that independent claim 1 is in allowable form. Reconsideration and allowance of claims 2-4, 8-11, 16 and 20-27 are respectfully requested.

-11-

The Office Action also rejected claims 1-5, 8-11 and 16-27 as being unpatentable under 35 U.S.C. 103(a) as being obvious over the Ryan application. With respect to claim 1, the Office Action alleged, along with the allegations made with respect to the anticipation rejection, that although the Ryan application is silent as to the exact difference between the elastin concentrations in each layer, the Ryan application does provide the general teaching that there is to be a difference between the two layers. Therefore, the Office Action concludes that it would have been well within the purview of one of ordinary skill in the art to optimize the concentration of elastin in each matrix layer, and the corresponding difference between the concentrations, as a matter of routine experimentation.

Applicants respectfully disagree that claim 1 is made obvious by the Ryan application. Claim 1 includes that at least one layer further comprises a reconstituted composition. Reconstituted compositions are defined as involving mixtures of synthetic and/or purified materials, possibly blended with fragmented natural materials, to form a non-natural material for incorporation into the composite. (See page 16, lines 16-19 of the application). The Office Action makes no allegation that the Ryan application discloses, teaches or suggests a reconstituted composition, and Applicants submit that the Ryan application does not disclose a reconstituted composition as defined in the application.

Since the Ryan application does not disclose, teach or suggest each and every element of claim 1, namely a reconstituted composition, claim 1 is not made obvious by the Ryan application. Reconsideration and allowance of claim 1 are respectfully requested.

The Office Action also rejected dependent claims 2-4, 8-11 and 16-27 as being obvious for the reasons stated with respect to independent claim 1 as well as other passages in the Ryan Application. While Applicants do not acquiesce to these rejections of the above-mentioned dependent claims, the rejections are moot in light of the fact that independent claim 1 is in allowable form. Reconsideration and allowance of claims 2-4, 8-11, 16-27 are respectfully requested.

If a telephone conference would be helpful in resolving any issues concerning this

-12-

communication, please contact Applicants' attorney of record, Hallie A. Finucane, at (612) 334-3222.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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